In the United States Court of Federal Claims

No. 99-644V, No. 99-631V, No. 99-660V, No. 99-639V, and No. 01-307V
(Filed: August 17, 2009)

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CLAUDIA ROTOLI,	*	
	*	
Petitioner,	*	
	*	
DAVID MYERS,	*	
	*	
Petitioner,	*	
	*	
COLLEEN TORBETT,	*	
	*	
Petitioner,	*	**Hepatitis B Vaccine; Autoimmune**
	*	**Hepatitis (AIH); Causation-in-Fact;**
MONA PORTER,	*	**Credibility Determinations Under**
	*	**Andreu; Medical Theory;**
Petitioner,	*	**Appropriate Temporal Relationship;**
	*	**Alternative Causation.**
ALLISON HAGER,	*	
	*	
Petitioner,	*	
	*	
v.	*	
	*	
SECRETARY OF HEALTH	*	
and HUMAN SERVICES,	*	
	*	
Respondent.	*	
* * * * * * * * * * * * * * * *	*	

Ronald Craig Homer, **Boston, MA, for petitioners.**

Althea Walker Davis, **U.S. Department of Justice, Washington, DC, with whom were *Tony West*, Assistant Attorney General, and *Timothy P. Garren,* Director, for defendant.**

COMBINED – OPINION AND ORDER[1]

FIRESTONE, *Judge*.

Pending before the court are the motions by the five petitioners, Claudia Rotoli, David Myers, Colleen Torbett, Mona Porter, and Allison Hager, for review of the special master's decisions denying them compensation under the National Vaccine Injury Compensation Program. Rotoli v. Sec'y of HHS, No. 99-644V, 2008 WL 4483739 (Fed. Cl. Spec. Mstr. Sept. 11, 2008); Myers v. Sec'y of HHS, No. 99-631V, 2008 WL 4483747 (Fed. Cl. Spec. Mstr. Sept. 11, 2008); Torbett v. Sec'y of HHS, No. 99-660V, 2008 WL 4483738 (Fed. Cl. Spec. Mstr. Sept. 11, 2008); Porter v. Sec'y of HHS, No. 99-639V, 2008 WL 4483740 (Fed. Cl. Spec. Mstr. Sept. 11, 2008); Hager v. Sec'y of HHS, No. 01-307V, 2008 WL 4763736 (Fed. Cl. Spec. Mstr. Oct. 15, 2008); National Childhood Vaccine Injury Act of 1986 ("Vaccine Act"), 42 U.S.C. §§ 300aa-1 to -34 (2004).

The petitioners allege that the hepatitis B vaccine, which they each received in three doses in the 1990s, caused them to suffer autoimmune hepatitis ("AIH")[2] and

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[1]Pursuant to Rule 18(b) of Appendix B of the Rules of the United States Court of Federal Claims ("RCFC, App. B"), this Opinion and Order is initially being filed under seal. The parties shall have fourteen days from the date of filing of this Opinion and Order to propose redactions of any of the information herein.

[2]AIH is "a chronic inflammatory disease of the liver, characterized by a loss of tolerance against hepatocytes leading to the destruction of hepatic parenchyma." Myers Ex. A Tab 2 (Michael P. Manns & Arndt Vogel, Autoimmune Hepatitis, From Mechanisms to Therapy, 43 Hepatology No. 2, Suppl. 1 S132 (2006)). In lay terms, AIH is a condition in which the immune system attacks the liver as if it is foreign tissue.

Throughout this Opinion and Order, exhibits labeled alphabetically (with numeric tabs) refer to exhibits submitted by the respondent in a given case (i.e., Rotoli Ex. A Tab 1), while those labeled numerically (with alphabetic tabs) are the petitioners' exhibits (i.e., Rotoli Ex. 1

associated injuries. Joint hearings were held in the five cases on September 17-19, 2007, and March 10-11, 2008. In each case, the special master found by a preponderance of the evidence that the petitioners had failed to establish a medical theory causally connecting the hepatitis B vaccine to AIH and that each individual petitioner had failed to demonstrate that the hepatitis B vaccine was the cause-in-fact of the injuries in his or her particular case. In their motions for review, the petitioners contend that the special master's decisions were arbitrary, capricious, and not in accordance with law. Oral argument on the motions for review was heard on July 22, 2009.

A single, consolidated Opinion and Order is being issued in all five cases because of the substantial overlap of the legal and factual issues in each. As discussed below, the court finds that the special master's decisions were not in accordance with law. As a result, the court will issue its own findings of fact and conclusions of law in each of the five cases.

STANDARDS OF REVIEW

Under the Vaccine Act, in reviewing a special master's decision on a motion for review, the Court of Federal Claims has jurisdiction to "undertake a review of the record of the proceedings" and may take any of the following actions:

> (A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,

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Tab A).

> (B) set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or
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> (C) remand the petition to the special master for further action in accordance with the court's direction.

42 U.S.C. § 300aa-12(e)(2); see also RCFC, App. B Rule 27. Thus, "the Court of Federal Claims reviews the decision of the special master to determine if it is 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.'" de Bazan v. Sec'y of HHS, 539 F.3d 1347, 1350 (Fed. Cir. 2008) (quoting 42 U.S.C. § 300aa-12(e)(2)(B)). Specifically, "[f]act findings are reviewed . . . under the arbitrary and capricious standard; legal questions under the 'not in accordance with law' standard; and discretionary rulings under the abuse of discretion standard."[3] Munn, 970 F.2d at 870 n.10, cited in, e.g., Pafford v. Sec'y of HHS, 451 F.3d 1352, 1355 (Fed. Cir. 2006).

The Federal Circuit has held that,

> [i]n general, reversible error is extremely difficult to demonstrate if the special master has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision. . . . [I]t is not . . . the role of [the reviewing] court to reweigh the factual evidence, or to assess whether the special master correctly evaluated the evidence. And of course [the reviewing court does] not examine the probative value of the evidence or the credibility of the witnesses. These are all matters within the purview of the fact finder.

Lampe v. Sec'y of HHS, 219 F.3d 1357, 1360 (Fed. Cir. 2000) (internal quotations

[3] "The latter will rarely come into play except where the special master excludes evidence." Munn v. Sec'y of HHS, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992).

omitted) (citing Hines v. Sec'y of HHS, 940 F.2d 1518, 1528 (Fed. Cir. 1991); Munn, 970 F.2d at 871)). However, as the Federal Circuit recently cautioned, a special master may not "frame her rejection of [a petitioner's] theory of causation under the rubric of a 'credibility' determination." Andreu v. Sec'y HHS, 569 F.3d 1367, 1379 (Fed. Cir. 2009). As the Federal Circuit explained,

> While considerable deference must be accorded to the credibility determinations of special masters, see Bradley v. Sec'y of [HHS], 991 F.2d 1570, 1575 (Fed. Cir. 1993), this does not mean that a special master can cloak the application of an erroneous legal standard in the guise of a credibility determination, and thereby shield it from appellate review. A trial court makes a credibility determination in order to assess the candor of a fact witness, not to evaluate whether an expert witness' medical theory is supported by the weight of epidemiological evidence. See Lampe . . . , 219 F.3d [at] 1373-74 . . . (Plager, J., dissenting) (noting that the issue is not one of "credibility" when a highly qualified expert presents a biologically plausible theory linking a claimant's injury to the DPT vaccine).

Andreu, 569 F.3d at 1379 (emphasis added).

If the Court of Federal Claims concludes that the special master's decision was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, the Court of Federal Claims may make its own factual findings, 42 U.S.C. § 300aa-12(e)(2)(B); de Bazan, 539 F.3d at 1350-51; Munn, 970 F.2d at 871-72, "[s]o long as the record contain[s] sufficient evidence upon which to base predicate findings of fact and the ultimate conclusion of causation." Althen v. Sec'y of HHS, 418 F.3d 1274, 1281 (Fed. Cir. 2005).

CAUSATION STANDARDS UNDER THE VACCINE ACT

The Vaccine Act created the National Vaccine Injury Compensation Program ("Vaccine Program"), "under which compensation may be paid for a vaccine-related injury or death." 42 U.S.C. § 300aa-10(a); Walther v. Sec'y of HHS, 485 F.3d 1146, 1149 (Fed. Cir. 2007). As part of the Vaccine Program, the Vaccine Injury Table ("Table") was developed, listing vaccines, injuries resulting therefrom, and time periods for onset of those injuries "for purposes of receiving compensation under the Program." 42 U.S.C. § 300aa-14; 42 C.F.R. § 100.3 (2009). In a so-called "Table case," "a petitioner who shows that he or she received a vaccination listed in the [Table], and suffered an injury listed in the Table within the time period prescribed by the Table gains a presumption of causation." Walther, 485 F.3d at 1149 (citing 42 U.S.C. § 300aa-11(c)(1)(C)(I); Pafford, 451 F.3d at 1355).

By contrast, if a petitioner received a vaccination listed in the Table but did not suffer an injury listed therein, the petitioner is considered to have an "off-Table case." In cases involving off-Table injuries, there is no presumption of causation. Under the Vaccine Act, a petitioner claiming that she "sustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table" must show that the injury "was caused by a vaccine" listed in the Table. 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(I). Thus, in an off-Table case, the petitioner must prove "causation-in-fact," de Bazan, 539 F.3d at 1351, meaning that she "suffered an injury that

was actually caused by the vaccine." Walther, 485 F.3d at 1149 (emphasis added). Because AIH is not listed in the Table as a covered illness, disability, injury or condition for the hepatitis B vaccine, 42 C.F.R. § 100.3, these five cases are off-Table cases, and the petitioners must prove causation-in-fact.

In Althen v. Secretary of Health and Human Services, the Federal Circuit clarified that, to meet her burden to prove causation-in-fact, a petitioner must

> show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury;[4] and (3) a showing of a proximate temporal relationship between vaccination and injury.[5]

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[4]Specifically, the Federal Circuit has held that "[a] persuasive medical theory is demonstrated by proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury, the logical sequence being supported by reputable medical or scientific explanation, i.e., evidence in the form of scientific studies or expert medical testimony." Althen, 418 F.3d at 1278 (quotation omitted); see also Knudsen v. Sec'y of HHS, 35 F.3d 543, 548 (Fed. Cir. 1994) ("This logical sequence of cause and effect must be supported by a sound and reliable medical or scientific explanation." (quotations omitted)).

The Federal Circuit has further explained the second prong of Althen thus:

> The second prong of the Althen . . . test is not without meaning. There may well be a circumstance where it is found that a vaccine can cause the injury at issue and where the injury was temporally proximate to the vaccination, but it is illogical to conclude that the injury was actually caused by the vaccine. A claimant could satisfy the first and third prongs without satisfying the second prong when medical records and medical opinions do not suggest that the vaccine caused the injury, or where the probability of coincidence or another cause prevents the claimant from proving that the vaccine caused the injury by preponderant evidence.

Capizzano v. Sec'y of HHS, 440 F.3d 1317, 1327 (Fed. Cir. 2006).

[5]The "proximate temporal relationship" standard requires "preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." de Bazan, 539 F.3d

418 F.3d at 1278; see 42 U.S.C. § 300aa-13(a)(1)(A) (preponderance of evidence standard as to petitioner). The three factors of the Althen test make up the petitioner's prima facie case for entitlement to compensation.[6] de Bazan, 539 F.3d at 1352. Once the petitioner has met her burden, "the burden shifts to the government to prove by a preponderance of the evidence that the petitioner's injury is due to factors unrelated to the . . . vaccine" ("alternative causation"). de Bazan, 539 F.3d at 1352 (internal quotation omitted) (citing 42 U.S.C. § 300aa-13(a)(1)(B) (preponderance of evidence standard as to causation by factors unrelated to the vaccine); Walther, 485 F.3d at 1150)).

The Federal Circuit "has interpreted the 'preponderance of the evidence' standard referred to in the Vaccine Act as one of proof by a simple preponderance, of 'more probable than not' causation." Althen, 418 F.3d at 1279. Of course, "[t]he government, like any defendant, is permitted to offer evidence to demonstrate the inadequacy of the petitioner's evidence on a requisite element of the petitioner's case-in-chief." de Bazan, 539 F.3d at 1353. However, the Federal Circuit has emphasized that "'close calls regarding causation are resolved in favor of injured claimants.'" Andreu, 569 F.3d at 1378 (quoting Capizzano, 440 F.3d at 1325-26).

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at 1352.

[6]The Federal Circuit has explained that, "[s]o long as the petitioner has satisfied all three prongs of the Althen test, she bears no burden to rule out possible alternative causes." de Bazan, 539 F.3d at 1352. However, "a petitioner may instead rule out possible alternative causes to prove causation-in-fact when evidence as to the Althen requirements is insufficient." de Bazan, 539 F.3d at 1352 n.3 (emphasis in original).

Importantly, preponderance of the evidence does not require "scientific certainty," and the findings of the special master or this court need not "meet the standards of the laboratorian." Bunting v. Sec'y of HHS, 931 F.2d 867, 873 (Fed. Cir. 1991) (quotation omitted). Instead, the Federal Circuit has held,

> [c]ausation in fact under the Vaccine Act is . . . based on the circumstances of the particular case, having no hard and fast per se scientific or medical rules. The determination of causation in fact under the Vaccine Act involves ascertaining whether a sequence of cause and effect is "logical" and legally probable, not medically or scientifically certain. . . . Thus, for example, causation can be found in vaccine cases based on epidemiological evidence and the clinical picture regarding the particular child without detailed medical and scientific exposition on the biological mechanisms.

Knudsen, 35 F.3d at 548-49 (citations omitted). The fact that a link between a vaccine and a particular injury is a "sequence hitherto unproven in medicine" will not bar recovery, because "the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body."[7] Althen, 418 F.3d at 1280. As the Federal Circuit has explained, in contrast to medical research, in which "attribution of causation is typically not made until a level of very near certainty – perhaps 95% probability – is achieved[,] . . . determination of causation in fact under the Vaccine Act involves ascertaining whether a sequence of cause and effect is 'logical' and legally probable, not medically or scientifically certain.'" Andreu, 569 F.3d at 1380 (both emphases in original; quotations

[7]Nor is it dispositive that the state of medical knowledge regarding a causal link between the vaccination and the illness can be characterized as "controversial." Bunting, 931 F.3d at 873.

omitted); see also Bunting, 931 F.3d at 873 ("The association of the administration of the . . . vaccine with the onset of these illnesses is not negated by the Medical Review's assertion of the absence of a 'controlled study.'").

Thus, circumstantial evidence may be used to prove causation by preponderant evidence, and "'identification and proof of specific biological mechanisms'" are not required. Althen, 418 F.3d at 1280 (quoting Knudsen, 35 F.3d at 549 ("The Court of Federal Claims is . . . not to be seen as a vehicle for ascertaining precisely how and why . . . vaccines sometimes destroy the health and lives of certain children while safely immunizing most others. This research is for scientists, engineers, and doctors working in hospitals, laboratories, medical institutes, pharmaceutical companies, and government agencies.")); Capizzano, 440 F.3d at 1324. Moreover, pursuant to 42 U.S.C. § 300aa-13(a)(1), a finding of preponderant evidence of causation-in-fact must be substantiated by medical records or by medical opinion.[8] Althen, 418 F.3d at 1279. Thus, a finding of causation may be based on a reliable medical opinion alone, even where there are no supporting studies; medical literature supporting causation-in-fact is not required, nor is medical documentation.[9] Althen, 418 F.3d at 1280.

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[8]42 U.S.C. § 300aa-13(a)(1) states, "The special master or court may not make . . . a finding [of preponderant evidence of causation] based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion."

[9]As the Federal Circuit recently noted, however,

> [a]lthough Althen and Capizzano make clear that a claimant need not produce medical literature or epidemiological evidence to establish causation under the

DISCUSSION

I. The Special Master's Rejection of the Petitioners' Evidence of Causation Violated the Federal Circuit's Standards Under Andreu.

As described above, the Federal Circuit recently held in Andreu v. Secretary of Health and Human Services that, "[w]hile considerable deference must be accorded to the credibility determinations of special masters, this does not mean that a special master can cloak the application of an erroneous legal standard in the guise of a credibility determination, and thereby shield it from appellate review." 569 F.3d at 1379 (citation omitted). The Federal Circuit in Andreu clarified that "[a] trial court makes a credibility determination in order to assess the candor of a fact witness, not to evaluate whether an expert witness' medical theory is supported by the weight of the epidemiological evidence." Id. (emphasis added) (citing Lampe, 219 F.3d at 1373-74 (Plager, J., dissenting) (noting that the issue is not one of "credibility" when a highly qualified expert presents a biologically plausible theory linking a claimant's injury to the DPT vaccine)).

In these five cases, the special master's analysis of the petitioners' evidence of causation ran afoul of the Federal Circuit's standards regarding credibility determinations.

> Vaccine Act, where such evidence is submitted, the special master can consider it in reaching an informed judgment as to whether a particular vaccination likely caused a particular injury. See Daubert[v. Merrell Dow Pharms., Inc.], 509 U.S. [579,] 593-97[(1993)] (noting that one factor in assessing the reliability of expert testimony is whether the theory espoused enjoys general acceptance within a relevant scientific community).

Andreu, 569 F.3d at 1379-80 ("The assessment of whether a proffered theory of causation is 'reputable' can involve assessment of the relevant scientific data.").

Just as the special master did in Andreu, the special master in these cases erroneously "cloak[ed]" much of his rejection of the petitioners' theory of causation "under the rubric of a 'credibility' determination" regarding Dr. Joseph A. Bellanti, the petitioners' expert witness. See Andreu, 569 F.3d at 1379.

These were not cases in which the special master was "assessing the candor of a fact witness," in which a credibility determination might have been appropriate. See id. Instead, Dr. Bellanti was a highly qualified expert witness whose extensive credentials are not in dispute. At the time of the hearings in this case, Dr. Bellanti was a Professor of Microbiology and Immunology and Pediatrics at Georgetown University Medical Center. Tr. 6; e.g., Rotoli Ex. 47 (Curriculum Vitae of Dr. Bellanti). He was also the Director of the International Center for Interdisciplinary Studies of Immunology at Georgetown University Medical Center. Tr. 6-7; e.g., Rotoli Ex. 47. He was also the Director of the Division of Immunology and Virology at the Department of Laboratory Medicine at the Georgetown University Hospital. E.g., Rotoli Ex. 47. He was involved in research, education, and in-patient care at Georgetown. Tr. 7. Among other professional organizations, Dr. Bellanti served on the American Board of Allergy and Immunology, where he was the pediatric component chairman alongside respondent's expert, Dr. Burton Zweiman, who served as Dr. Bellanti's counterpart in internal medicine. Tr. 11. Though Dr. Bellanti is admittedly not a gastroenterologist nor a hepatologist, he is an expert in the field of immunology and is qualified to discuss the pathways of autoimmune

disease.[10] As the Federal Circuit emphasized, where a highly qualified expert such as Dr. Bellanti presents a biologically plausible theory of causation in a vaccine case, the issue is not one of credibility. Andreu, 569 F.3d at 1379 (citing Lampe, 219 F.3d at 1373-74).

In these cases, however, the special master erroneously founded his rejection of the petitioners' theory of causation on his assessment of Dr. Bellanti's "poor" credibility. E.g., Rotoli, 2008 WL 4483739 at *7. The special master's discussion of Dr. Bellanti's credibility permeated his analysis of the petitioners' claims. Most egregiously, the special master included a nine-page section – a substantial portion of the total length of each decision – entitled "Additional Comments Regarding Dr. Bellanti," in which he questioned not only "Dr. Bellanti's persuasiveness but also his truthfulness" as a result of various weaknesses in the evidence underlying Dr. Bellanti's claims and Dr. Bellanti's "demeanor." E.g., Rotoli, 2008 WL 4483739 at **22-30; see also, e.g., id. at *29 ("[T]he evidence from each case solely supports a finding that Dr. Bellanti lacks credibility."). In addition to the portion of each decision devoted expressly to Dr. Bellanti's credibility, references to Dr. Bellanti's credibility also pervaded the special master's analyses of the

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[10]Even the special master noted that,

> [i]n other cases, Dr. Bellanti has offered opinions that a vaccine caused a particular condition that Special Masters have found persuasive. E.g., Keenan v. Sec'y of [HHS], No. 99-561V, 2007 WL 1231592 *10 (Fed.Cl.Spec.Mstr. Apr. 5, 2007); Bowes v. Sec'y of [HHS], No. 01-481V, 2006 WL 2849816 (Fed.Cl.Spec.Mstr. Sept. 8, 2006).

E.g., Rotoli, 2008 WL 4483739 at *30.

medical theory proposed by all five petitioners and of the specific evidence of causation in each of the five cases.[11] In reviewing the evidence (including the medical literature) in the five cases, the special master – rather than simply evaluating whether Dr. Bellanti's medical theory of causation was supported by the weight of that evidence – went so far as to conclude that the "questions about the basis for Dr. Bellanti's statements . . . have led to a question about Dr. Bellanti's veracity." E.g., Rotoli, 2008 WL 4483739 at *30 (emphasis added). Indeed, by couching his rejection of Dr. Bellanti's testimony in terms of credibility, the special master apparently expected his analysis to be "virtually not reviewable on appeal." See, e.g., Rotoli, 2008 WL 4483739 at *4 (citing Bradley, 991 F.2d at 1575).

In view of the foregoing, the court finds that the special master erroneously used his assessment of Dr. Bellanti's credibility – an assessment that should be reserved for "assessing the candor of a fact witness" – as a basis for rejecting Dr. Bellanti's expert testimony regarding causation, in violation of Andreu. 569 F.3d at 1379. Moreover, the court finds that the pervasiveness of the comments regarding Dr. Bellanti's credibility throughout the special master's decisions – both in his discussion of the medical theory put forth by all five petitioners and in his discussions of the specific evidence of causation

[11]For example, with regard to the petitioners' medical theory causally linking the hepatitis B vaccine with AIH in general, the special master cited Dr. Bellanti's lack of credibility as a reason to reject molecular mimicry, Rotoli, 2008 WL 4483739 at *7, and challenge-rechallenge, id. at *16. In Ms. Rotoli's case, the special master also pointed to Dr. Bellanti's credibility as a reason to dismiss Ms. Rotoli's arguments regarding the temporal relationship of her symptoms to the vaccine. Id. at *17.

in each of the five individual cases – makes it impossible to review the special master's evaluation of the evidence separately from his erroneous credibility determination. The special master's error has tainted his entire causation analysis. Accordingly, the court finds that the special master's framing of his rejection of the petitioners' theory of causation "under the rubric of a 'credibility' determination," see Andreu, 569 F.3d at 1379, constituted a legal error allowing the court to set aside the special master's findings under 42 U.S.C. § 300aa-12(e)(2)(B).

Rather than remand to the special master for a redetermination regarding causation, the court will issue its own findings in these cases, as authorized under 42 U.S.C. § 300aa-12(e)(2)(B) (permitting the Court of Federal Claims to "issue its own findings of fact and conclusions of law") and under RCFC, App. B Rule 27 (same). The Federal Circuit has recognized that the Court of Federal Claims may make its own findings of fact in circumstances in which it has concluded that the special master's decision was arbitrary and capricious or not otherwise in accordance with law "and that it is necessary for the [Court of Federal Claims] to substitute its own findings of fact." Munn, 970 F.2d at 870. While remand to the special master for a redetermination regarding causation would ordinarily be appropriate, given the protracted, ten-year history of this litigation and the impossibility of separating the special master's error regarding Dr. Bellanti's credibility from the rest of the special master's analysis, the court has deemed it appropriate it to make its own findings as to causation in these five cases.

Moreover, because the credibility of fact witnesses is not at issue in these cases, as discussed above, and the court has the benefit of a thorough record, including the hearing transcript, the expert reports, the medical literature, and the petitioners' medical records, the court is well-situated to make such findings. Althen, 418 F.3d at 1281 ("[B]ecause the special master's decision was not in accordance with law, the trial court was permitted to review the evidence anew and come to its own conclusion. . . . So long as the record contained sufficient evidence upon which to base predicate findings of fact and the ultimate conclusion of causation, which it did, the trial court was not required to remand." (citations and footnote omitted)). Accordingly, the court's findings of fact and conclusions of law regarding causation are set forth, below.

II. The Court's Findings as to Causation-in-Fact

Having determined, as discussed above, that the special master's findings were irremediably tainted with a legally improper credibility determination, the court will now make its own findings of fact and conclusions of law regarding the merits of the petitioners' claims that the hepatitis B vaccine was the cause-in-fact of their injuries. To that end, the court will first evaluate the petitioners' proposed medical theory by which the hepatitis B vaccine can cause AIH, for which the discussion will be the same in all five cases, followed by an evaluation of the evidence of causation in each of the five individual cases.

A. Medical Theory

The first prong of the Althen causation-in-fact test – preponderant evidence of "a medical theory causally connecting the vaccination and the injury," Althen, 418 F.3d at 1278 – addresses whether the vaccine at issue can cause the type of injury alleged. Pafford, 451 F. 3d at 1355-56. Because the petitioners and the government in all five of the instant cases relied upon essentially the same expert witnesses and supporting evidence as to whether the vaccine can cause the injury alleged, this portion of the court's analysis applies to all of the petitioners whose claims are included in this Opinion and Order.

For the reasons set forth below, the court finds that the petitioners met their burden to demonstrate a reliable medical theory causally connecting the hepatitis B vaccine with AIH. Specifically, the court finds that the petitioners set forth sufficient evidence that the hepatitis B virus can cause AIH, and therefore the hepatitis B vaccine may also be presumed to be capable of doing so. Furthermore, the court finds that the petitioners presented sufficient evidence that the hepatitis B vaccine could cause AIH via dysfunction of the CD4+ regulatory T cells in genetically predisposed individuals.

1. The Petitioners' Proposed Medical Theory

In these five cases, the petitioners submitted the expert report and testimony of Dr. Bellanti, whose expert credentials as an immunologist have already been described, above. In his report, Dr. Bellanti stated,

> Based upon my review of the experimental and clinical studies related to the environmental, genetic, and immunologic factors that play a role in the pathogenesis of autoimmune liver disease, it is my opinion to a reasonable degree of medical and scientific probability that [hepatitis B vaccine] can cause or significantly contribute to the development of [AIH].[12]

Rotoli Ex. 46 at 6.[13]

Specifically, Dr. Bellanti stated,

> There are a number of reasons for my opinion.
>
> 1. Infection with each of the hepatitis viruses (A, B and C) has been reported to cause [AIH]. Specifically germane to the present cases is the fact that infection with hepatitis B virus is known to cause [AIH], and generally, if a wild virus infection can cause an autoimmune disease, it should be assumed that the vaccine can also lead to autoimmunity in some susceptible individuals. Since vaccines include the infecting agents (whether attenuated, killed, modified, or recombinant) that can cause autoimmunity, by the same token, through any of the mechanisms discussed below, the vaccines can also stimulate autoreactivity;
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> 2. Vaccines in general can cause autoimmune conditions, and [AIH] is such a condition;
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> 3. There are other components in the [hepatitis B vaccine], besides the [hepatitis B] surface antigen, that can cause autoimmune reactions in some individuals, such as yeast, aluminum and thimerosal. It is biologically plausible for [hepatitis B vaccine] to result in [AIH] in some susceptible individuals; and

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[12]Dr. Bellanti further testified that, in his opinion, the hepatitis B vaccine was likely the cause of the petitioners' injuries in the five individual cases, as will be discussed below.

[13]The general causation sections of Dr. Bellanti's reports were virtually the same in each case. For the sake of simplicity, in discussing the petitioners' medical theory, the court will cite to the reports, exhibits, and special master's decision in Ms. Rotoli's case.

> 4. There are reports in the literature of positive rechallenge[14] where [hepatitis B vaccine] has been reported to cause various autoimmune conditions.

Rotoli Ex. 46 at 3.

In support of his contention that the hepatitis B virus is known to cause AIH, Dr. Bellanti pointed to the reference to such a connection in a chapter by Michael P. Manns et al. in a textbook edited by Noel Rose and Ian Mackay. Rotoli Ex. 70 at 511 ("Autoimmune Diseases: The Liver," by Michael P. Manns et al., in The Autoimmune Diseases, Noel Rose & Ian Mackay, eds. (3d ed. 1998) ("[AIH] is one entity of chronic hepatitis. Most cases of chronic hepatitis are due to viral infections caused by hepatitis viruses B, C, and D.")). The assertion in the textbook was based on two articles, one by Hopf and Möller from 1984 and the other by Laskus and Slusarczky from 1989. Dr. Bellanti also pointed to an article by Dr. Edward L. Krawitt, who is among the world's leading researchers in AIH, whose 2006 review of "Autoimmune Hepatitis" in the New England Journal of Medicine, cited by all of the experts in this case, states that "the most convincing evidence [identifying an infectious agent triggering AIH] is related to hepatitis viruses." Rotoli Ex. 46 Tab A at 1 (emphasis added). Finally, Dr. Bellanti relied upon two additional articles in support of his assertion that the hepatitis B virus can cause AIH – one by Antal Csepregi et al. from 2005, reporting one case of exacerbation of AIH with administration of the Twinrix vaccine, which contains a vaccine against both

[14] "A rechallenge event occurs when a patient who had an adverse reaction to a vaccine suffers worsened symptoms after an additional injection of the vaccine." Capizzano, 440 F.3d at 1322.

hepatitis A and hepatitis B (Rotoli Ex. 77), and the other by Valerio Nobili et al. from 2006, reporting one case of a child in Senegal who had both a chronic hepatitis B infection and AIH (Rotoli Ex. 83).

Dr. Bellanti then described various mechanisms by which infections and vaccines can cause autoimmune disease – molecular mimicry, bystander activation, polyclonal activation, and dysfunction of CD4+ regulatory T cells (or "T-reg cell dysfunction"). Rotoli Ex. 46 at 4. Over the course of the hearings in these cases, the last theory, CD4+ regulatory T cell dysfunction, rose to the forefront as a promising theory by which AIH might be triggered by a vaccine such as hepatitis B.[15] With regard to the T-reg cell theory in particular, Dr. Bellanti explained,

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[15]With regard to the other three mechanisms, Dr. Bellanti stated,

> There are a number of recognized mechanisms by which infections and vaccines can cause autoimmune disease. The most common is the concept of molecular mimicry . . . . The finding of molecular mimicry in which cross-reactivity between epitopes of hepatitis viruses and certain liver antigens exists adds credence to a hypothesis for the pathogenesis of [AIH].
>
> Another mechanism involves . . . bystander activation, where the vaccine, or some component[], causes tissue damage. The tissue damage leads to the exposure of antigens to which the body is not tolerized and believes is "foreign[."] When the immune system fails to recognize the cryptic antigens as "self," it assaults the self-antigens in a self-perpetuating destructive attack.
>
> Polyclonal activation is another potential pathogenic mechanism of autoimmunity that has received attention in numerous articles. In this situation, adjuvants in the vaccines potentiate the immune response which then becomes misdirected. Some of the adjuvants, like thimerosal, can even induce autoimmune phenomena in animal models without an infecting antigen being present.

Rotoli Ex. 46 at 4.

> A more recent theoretical mechanism involves participation of CD4+ regulatory T cells. These have been identified as the cells that maintain immunologic tolerance, the property of the immune system which distinguishes one's own tissues as self from those exogenous materials which are recognized as "non-self." The failure of, or escape from, normal suppression of reactivity against "self" has an essential role in the development of autoimmune disease. Studies suggest that a decrease in the number of regulatory T cells and their ability to expand may lead to autoimmune liver disease.

Rotoli Ex. 46 at 4. Dr. Bellanti explained how the CD4+ regulatory T cell theory might be linked to the hepatitis B vaccine thus:

> [T]he regulation of the immune system, how antigen is recognized, processed and delivered determines in all cases the ultimate success or failure of elimination, and that ties in with autoimmune disease . . . . [I]n certain genetically predisposed individuals, their response to certain vaccines leads to adverse effects due to this genetic inability to handle the antigen as [compared with] that bell-shaped curve – 95-99 percent of the population. There [are] these outliers that are responding differently, and those are the unfortunate ones that get into trouble with vaccines.

Tr. 108-09. In support of the T-reg cell dysfunction theory, Dr. Bellanti pointed to an article by Maria Serena Longhi et al., entitled "Impairment of CD4+ CD25+ regulatory T-cells in autoimmune liver disease," 41 Journal of Hepatology 31-37 (2004) ("Longhi article"). Rotoli Ex. 97. The Longhi article found that T-reg cells were significantly lower in number and ability to expand in patients with autoimmune liver disease than in controls. Id.

2. The Respondent's Evidence

The respondent, in turn, submitted the expert reports and testimony of Dr. Raymond Koff, a gastroenterologist and Clinical Professor of Medicine at the University

of Connecticut School of Medicine, Rotoli Ex. D, and Dr. Burton Zweiman, an Emeritus Professor of Medicine and Neurology at the University of Pennsylvania School of Medicine.[16] Rotoli Ex. B. Both Dr. Koff and Dr. Zweiman testified that they believe that medical and scientific evidence has not established that the hepatitis B vaccine can cause AIH. Dr. Zweiman indicated that he would require stronger epidemiological evidence, such as an epidemiological study demonstrating statistical significance, before he would be convinced that the hepatitis B vaccine causes AIH. Tr. 169-71. Dr. Zweiman also indicated that, contrary to Dr. Bellanti's assertion, there is much less convincing evidence that chronic AIH results from chronic hepatitis B infection than from hepatitis A or hepatitis C infection. Similarly, Dr. Koff stated that there is no support in the literature "for the concept that acute hepatitis B virus infection can be a trigger of [AIH]." Rotoli Ex. C at 2. With regard to Dr. Bellanti's rechallenge assertion, Dr. Zweiman pointed to a 2005 study by J. Beran et al. in the Central European Journal of Public Health, in which "a group of patients with pre-existent [chronic AIH] experienced no worsening of their [chronic AIH] following receipt of the [hepatitis B vaccine] injections."[17] Rotoli Ex. A at

[16]In Ms. Hager's case, the respondent also submitted the expert report and testimony of Dr. Melvin Berger, a Professor of Pediatrics and Pathology at Case Western Reserve University School of Medicine in Cleveland, OH.

[17]The Beran study was undertaken to determine, in light of the risk of disease exacerbation or relapse if patients with AIH contract the hepatitis A or B viruses, whether it is appropriate to immunize such patients with a combined hepatitis A and hepatitis B vaccine. Rotoli Ex. 1004. Indeed, Dr. Zweiman testified that "it is generally recommended that all individuals with chronic inflammatory disease of the liver receive a course of hepatitis B immunization." Tr. 129.

4; Rotoli Ex. 1004. Finally, with regard to the T-reg cell dysfunction theory, Dr. Zweiman noted that Dr. Bellanti had "discussed nicely" the T-regulatory cell theory, Tr. 863, but emphasized that the Longhi article studied people who had AIH, not people who received the hepatitis B vaccine, and that "nobody has ever reported whether or not hepatitis immunization induces alteration of immunoregulatory T-cells." Tr. 1100, 1132.

3. The Petitioners Met Their Burden to Provide a Medical Theory Causally Connecting the Hepatitis B Vaccine to AIH.

As noted above, to meet their burden as to causation-in-fact, petitioners must demonstrate a medical theory causally connecting the vaccine and the alleged injury that is "supported by reputable medical or scientific explanation, i.e., evidence in the form of scientific studies or expert medical testimony." Althen, 418 F.3d at 1278 (emphasis added; quotation omitted). In these five cases, the petitioners put forth the expert medical testimony of Dr. Bellanti, who stated that, in his opinion, the hepatitis B vaccine can cause or significantly contribute to the development of AIH. Dr. Bellanti offered a number of reasons for his opinion – most significantly that, in light of the evidence that the hepatitis B virus can cause AIH, the hepatitis B vaccine can also be presumed to be capable of causing AIH, and that vaccine-induced AIH might be brought about by or

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However, the petitioners argue that the Beran study, which examined only ten patients with AIH, did not have a sufficiently large sample size to detect the rare reaction of people whose genetic makeup makes them susceptible to contracting AIH triggered by the hepatitis B vaccine. As the petitioners emphasize, they are not claiming that all cases of AIH are related to the hepatitis B vaccine, but that the vaccine can trigger AIH in certain genetically predisposed individuals.

associated with the dysfunction of the CD4+ T-regulatory cells in genetically susceptible individuals. In turn, in support of each of the reasons for his opinion, Dr. Bellanti offered medical literature and/or scientific studies. The court finds that the evidence presented by the petitioners is sufficient to meet their burden with regard to a medical theory causally linking the hepatitis B vaccine with AIH.

The respondent's attack of the petitioners' evidence of a medical theory was largely focused on the quantum of evidence in the scientific literature underlying Dr. Bellanti's assertions. They did not present any medical literature that negated Dr. Bellanti's medical theory. Instead, they emphasized the fact that no link between the hepatitis B vaccine and AIH has been directly proven in the literature. In addition, the respondent attempted to undermine the articles offered by the petitioners in support of the inferential building blocks of Dr. Bellanti's theory. For example, with regard to Dr. Bellanti's assertion, based on an established textbook, that the hepatitis B virus has been shown to cause AIH, the respondent's expert, Dr. Koff, questioned the findings of each of the articles underlying the statement in the Rose and Mackay textbook to that effect, as well as of each of the other supporting articles put forth by the petitioners.[18] The

[18]Specifically, with regard to the article by Hopf and Möller, Dr. Koff indicated, based on his translation of the title of the article, which was written in German, but without having read the article, that the patient involved likely had chronic hepatitis B rather than AIH. Tr. 458-59. With regard to the article by Laskus and Slusarczky, Dr. Koff testified that, because there was no testing for hepatitis C at the time, it was possible that what was reported in the article as hepatitis B-related AIH could have been hepatitis C-related AIH instead. Tr. 459-60. Similarly, with regard to the articles by Csepregi and Nobili, submitted by Dr. Bellanti in support of his assertion that the hepatitis B virus causes AIH, the respondent's experts testified that the reports, which

respondent concluded that the paucity of reports of the hepatitis B virus causing AIH in the literature meant that a causal relationship was not indicated. Likewise, with regard to Dr. Bellanti's assertion that the hepatitis B vaccine might trigger AIH by way of dysfunction in the CD4+ T-regulatory cells in genetically susceptible individuals, the respondent did not contend that the theory was not sound. Instead, the respondent's expert, Dr. Zweiman, testified that "nobody has ever reported whether or not hepatitis immunization induces alteration of immunoregulatory T-cells." Tr. 1100, 1132.

The court is not persuaded by the respondent's attempt to undermine the petitioners' medical theory by chipping away at the quantity of evidence in the literature supporting Dr. Bellanti's assertions. As the Federal Circuit has recently emphasized, "'in a field bereft of complete and direct proof of how vaccines affect the human body,' a paucity of medical literature supporting a particular theory of causation cannot serve as a bar to recovery." Andreu, 569 F.3d at 1379 (emphasis added) (quoting Althen, 418 F.3d at 1280; citing Capizzano, 440 F.3d at 1324, and Daubert, 509 U.S. at 593 ("[I]n some

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each described only one patient, did not contain any meaningful analysis of causation. See, e.g., Tr. 1144-49.

Finally, with regard to Dr. Krawitt's article stating that "the most convincing evidence [identifying an infectious agent triggering AIH] is related to hepatitis viruses," Rotoli Ex. 46 Tab A at 1, the respondent's experts pointed out that the articles cited in support of this statement indicate only that AIH has been associated with hepatitis A infection and hepatitis C infection. Dr. Koff recounted that, between sessions of hearings in these cases, he spoke to Dr. Krawitt and two other experts in AIH, all of whom told Dr. Koff that they were not aware of the hepatitis B virus causing AIH. Tr. 989-92. The court is deeply suspicious of the conclusions the respondent would draw from Dr. Koff's description of what he was told in out-of-court conversations with Dr. Krawitt and others, especially given that the substance of those conversations varied from the statements in Dr. Krawitt's own writings.

instances well-grounded but innovative theories will not have been published. . . . Some propositions, moreover, are too particular, too new, or of too limited interest to be published.")). Similarly, the Federal Circuit has long held that a petitioner may recover even where the causal link between the vaccine and the particular injury was "a sequence hitherto unproven in medicine." Althen, 418 F.3d at 1280.

In light of the Federal Circuit's clear guidance that a medical theory can be found even where scientific studies on the subject are limited and direct proof is nonexistent, the court finds that in these cases, Dr. Bellanti's expert testimony regarding a medical theory causally connecting the hepatitis B vaccine and AIH was supported by sufficient scientific evidence to sustain a finding that the petitioners met their preponderant evidence burden.

Specifically, with regard to Dr. Bellanti's assertion that because the hepatitis B virus has been shown to cause AIH, the hepatitis B vaccine can be presumed to be similarly capable of causing AIH, contrary to the respondent's view, the fact that only a handful of cases linking the hepatitis B virus and AIH have been reported is not fatal to Dr. Bellanti's claim. As the petitioners correctly argue, the respondent's expert, Dr. Koff, himself explained that the undisputed link between the hepatitis A virus and AIH is supported by an equally small number of case reports. In Dr. Koff's words, "[i]f you look at the totality of the literature in which hepatitis A virus infection has been followed by AIH, you can put that number of cases in a corner of your eye, and you won't feel it. There may be six or seven cases." Tr. 429. Nonetheless, it is undisputed that that small

number of cases is sufficient to support an accepted link between the hepatitis A virus and AIH. By the same token, in support of Dr. Bellanti's expert opinion that the hepatitis B virus can cause AIH, the petitioners identified a reference in the textbook edited by Rose and Mackay stating that the hepatitis B virus has been implicated in chronic AIH, which in turn was supported by articles by Hopf and Möller and by Laskus and Slusarczky. When asked to identify further support for the proposition, Dr. Bellanti submitted additional case reports in articles by Csepregi and Nobili. Thus, the court finds that the petitioners submitted sufficient medical evidence of Dr. Bellanti's assertion regarding the hepatitis B virus.

Moreover, as the Federal Circuit has explained, in contrast to medical research, in which "attribution of causation is typically not made until a level of very near certainty – perhaps 95% probability – is achieved[,] . . . determination of causation in fact under the Vaccine Act involves ascertaining whether a sequence of cause and effect is 'logical' and legally probable, not medically or scientifically certain.'" Andreu, 569 F.3d at 1380 (both emphases in original; quotations omitted). As a result, the court finds that, although Dr. Bellanti's expert testimony that the hepatitis B vaccine can be presumed to be capable of causing AIH based on the link between the hepatitis B virus and AIH has not been directly proven in the literature, where, as here, there is no evidence to negate the theory, the petitioners have met their burden of demonstrating that it is "logical and legally probable," regardless of whether it has been shown to be "medically or scientifically certain." Andreu, 569 F.3d at 1380 (quotation and emphasis omitted).

The court also finds that the petitioners have set forth sufficient evidence in support of Dr. Bellanti's expert testimony that AIH might be brought about by or associated with the dysfunction of the CD4+ T-regulatory cells in genetically susceptible individuals, whose susceptibility might, in turn, be triggered by the introduction of the hepatitis B vaccine. As an initial matter, the court reiterates that, under Federal Circuit precedent, the petitioners are not required to provide "detailed medical and scientific exposition on the biological mechanisms." Knudsen, 35 F.3d at 548-49 (citations omitted); see also Althen, 418 F.3d at 1280 ("identification and proof of specific biological mechanisms" are not required). In these cases, Dr. Bellanti indicated that research regarding the function and dysfunction of T-regulatory cells including CD4+ cells is a "recent theoretical mechanism" currently being explored by scientists. Rotoli Ex. 46 at 4. Especially in light of the Longhi article connecting T-regulatory cell dysfunction with AIH, Dr. Zweiman did not disagree with Dr. Bellanti that CD4+ T-regulatory cell dysfunction was a possible pathway by which the hepatitis B vaccine might be found to cause AIH. Instead, he merely testified that "nobody has ever reported whether or not hepatitis immunization induces alteration of immunoregulatory T-cells." Tr. 1100, 1132. Again, the court finds that, although Dr. Bellanti's theory that CD4+ T-regulatory cell function could play a role in causally linking the hepatitis B vaccine and AIH has not, as Dr. Bellanti freely admitted, been directly proven by scientific studies, the petitioners have met their burden of demonstrating that the theory is "logical and legally probable," regardless of whether it has been shown to be "medically or scientifically

certain." Andreu, 569 F.3d at 1380 (quotation and emphasis omitted).

Finally, the respondent's expert, Dr. Zweiman, indicated that he would require strong epidemiological evidence, such as a study demonstrating statistical significance, before he could be convinced that the hepatitis B vaccine causes AIH. Tr. 169-71. However, the Federal Circuit has definitively held that "requiring 'epidemiologic studies . . . or general acceptance in the scientific or medical communities . . . impermissibly raises a claimant's burden under the Vaccine Act and hinders the system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants." Andreu, 569 F.3d at 1380 (quoting Capizzano, 440 F.3d at 1325-26). Accordingly, the court will not hold the petitioners to the impermissibly high burden of proof urged by the respondent. In conclusion, for the reasons set forth above, the court finds that the petitioners have met their burden under Althen to provide a logical and legally probable medical theory causally connecting the hepatitis B vaccine with AIH. See Andreu, 569 F.3d at 1380; Althen, 418 F.3d at 1278.

B. Specific Causation

Having found, as discussed above, that the petitioners have set forth sufficient evidence to meet their burden as to a medical theory, the court will now consider the evidence regarding the two remaining prongs of Althen – "a logical sequence of cause and effect showing that the vaccination was the reason for the injury" and "a showing of a proximate temporal relationship between vaccination and injury" – in each of the five individual cases. 418 F.3d at 1278. The court's facts and findings specific to each petitioner will be addressed in detail below.

1. Claudia Rotoli (No. 99-644V)

a) Facts and Expert Testimony

The undisputed facts relevant to Claudia Rotoli's case are briefly summarized below. Ms. Rotoli was born on January 25, 1969. Between March 1984 and 1994, she was treated for various conditions, including dry, itchy skin and rashes, neck, back and shoulder pain, and anxiety and depression. In 1994, Ms. Rotoli decided to attend school to become a medical assistant. In preparation for her enrollment, she received three doses of the hepatitis B vaccine, beginning on October 10, 1994. On October 21, 1994, Ms. Rotoli reported coughing, congestion, fever, and later reported a low grade fever and episodes of shakes and extreme weakness. Ms. Rotoli received her second dose of the hepatitis B vaccine on November 9, 1994. Approximately two months later, she was treated for a prolonged upper respiratory infection, bronchitis and conjunctivitis. A June 1995 report indicated that Ms. Rotoli started having pain in her right upper quadrant in May 1995.

On May 1, 1995, Ms. Rotoli received her third dose of the hepatitis B vaccine. On May 9, 1995, Ms. Rotoli donated blood, and on May 19, 1995, she was informed by the blood service that her blood contained an elevated amount of the enzyme alanine aminotransferase ("ALT"), elevation of which is consistent with some forms of liver disease. Blood tests from May 25, 1995 confirmed Ms. Rotoli's elevated ALT level and indicated other enzymes were also elevated. At that point, a doctor diagnosed hepatitis of unknown origin. Blood tests from May 31, 1995 also showed non-normal liver function.

The May 31, 1995 tests also indicated that she did not develop antibodies to the hepatitis B surface antigen, meaning that she did not respond to the vaccine.[19]

On June 20, 1995, Ms. Rotoli saw Dr. Katz, a gastroenterologist, who thought that Ms. Rotoli might have AIH and ordered tests for anti-nuclear antibodies ("ANA") to exclude this diagnosis. Ms. Rotoli's ANA test was positive. On June 29, 1995, a biopsy of Ms. Rotoli's liver revealed that she had chronic, active hepatitis with fibrosis and moderate necrosis. In July 1995, Dr. Katz diagnosed Ms. Rotoli with AIH and started her on prednisone, a steroid used to moderate the reaction of the immune system; Dr. Katz added Imuran later that month.

Ms. Rotoli continued to experience numerous health problems, including liver problems. In October 1996, she was diagnosed with Sjogren's disease. In 1997, she was diagnosed with systemic lupus erythematous, another autoimmune disorder. Finally, in 1998, she was diagnosed with central nervous system lupus. She now has deep pain and fatigue, skin infections, discoid lupus, diminished eyesight, and lesions on the white matter in her brain. She was removed from a liver transplant list after her diagnosis of lupus, and she is now terminally ill.

Based on these undisputed facts, Dr. Bellanti testified that it was his opinion "to a

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[19]The petitioners presented some evidence to show that non-responsiveness to the hepatitis B vaccine may correlate with a propensity for autoimmune illness. Rotoli Ex. 95 (Cesare Belloni et al., No Evidence of Autoimmunity in 6-Year-Old Children Immunized at Birth with Recombinant Hepatitis B Vaccine, 110 Pediatrics 1, 1-4 (July 2002) ("[A] high frequency (30%) of autoantibodies, in particular SMA, was observed in the nonresponder children. The SMA-positive children carried [a] haplotype [that is] a well-known predisposing factor for autoimmune disorders.").

reasonable degree of medical and scientific probability" that the hepatitis B vaccine "caused or significantly contributed to the development of the [AIH] in [Ms. Rotoli]." Tr. 590-91. Dr. Bellanti stated that Ms. Rotoli "has both evidence of [AIH] and systemic lupus with some overlap symptoms" and that "[t]he temporal relationship between her immunizations and the onset of symptoms is appropriate, and there's no other likely cause identifiable in the record." Tr. 591.

Based on the same undisputed facts, the respondent's expert, Dr. Koff, testified that, in his opinion, Ms. Rotoli's fibrosis established that her AIH began long before she received the hepatitis B vaccine, pointing to the presence of extensive fibrosis in her June 29, 1995 liver biopsy. As a result, Dr. Koff concluded, the hepatitis B vaccine could not have caused her AIH.

b) Ms. Rotoli Established a Proximate Temporal Relationship Between the Vaccine and Her Injuries by a Preponderance of the Evidence.

As noted above, as part of the petitioner's prima facie case of causation-in-fact, Althen requires "a showing of a proximate temporal relationship between vaccination and injury," 418 F.3d at 1278, defined as "preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." de Bazan, 539 F.3d at 1352. The court finds that Ms. Rotoli met her burden to show a medically acceptable temporal relationship between the vaccine and the onset of her injuries, as required under Althen. Dr. Bellanti testified that a reasonable time to expect an adverse

reaction is roughly fourteen to forty days after receipt of a dose of a vaccination. Tr. 34. The undisputed evidence showed that, eleven days after receiving her first dose of the vaccine on October 10, 1994, Ms. Rotoli reported coughing, congestion, and a fever. Approximately two months after her receipt on November 9, 1994 of her second dose of the vaccine, Ms. Rotoli was treated for a prolonged upper respiratory infection. She received her third dose of the vaccine on May 1, 1995. Around that time, she began having right upper quadrant pain, and blood work from May 9, 1995 indicated elevated levels of ALT. A June 20, 1995 test for ANA was positive, indicating a diagnosis of AIH. A June 29, 1995 biopsy revealed that Ms. Rotoli had chronic, active hepatitis with fibrosis and moderate necrosis. Dr. Bellanti testified that he believed that the temporal relationship between Ms. Rotoli's immunizations and the onset of her symptoms was therefore medically appropriate.

The respondent disputed the temporal relationship between Ms. Rotoli's symptoms and the vaccine on the basis of Dr. Koff's testimony that Ms. Rotoli's liver biopsy on June 29, 1995 (eight-and-a-half months after her first vaccination on October 10, 1994) showed that she already had active hepatitis with such extensive fibrosis that it had to have predated the vaccination. In response to Dr. Koff's testimony, the petitioners pointed to an article (presented by the respondent as an attachment to Dr. Zweiman's report) in the Journal of Hepatology by Hans-Iko Huppertz et al., to show that fibrosis could develop in as little as fourteen to sixteen weeks. Rotoli Ex. A Tab 5; see also Rotoli Ex. 98. In the Huppertz article, a seven-year-old subject developed AIH after

being infected with the hepatitis A virus, and fibrosis was seen in a biopsy sixteen weeks later (ten weeks after the onset of jaundice, which, in turn, developed six weeks after the "onset of hyperbilirubinemia"). Rotoli Ex. A Tab 5. In light of the evidence in the Huppertz article that fibrosis might be able to form in as little as sixteen weeks, as well as Dr. Bellanti's testimony regarding the uncertain etiology of AIH and the variability of clinical manifestations of the disease, the court finds that Dr. Koff's testimony that Ms. Rotoli's AIH must have predated her vaccinations was unpersuasive.

Thus, in addition to finding that the petitioners have met their burden of showing a medical theory causally connecting the vaccine and AIH, the court finds that Ms. Rotoli met her burden under Althen to establish a medically acceptable temporal relationship between the hepatitis B vaccinations and the onset of her AIH. In addition, in setting forth the medical theory and temporal relationship, Ms. Rotoli established by a preponderance of the evidence a logical sequence of cause and effect showing that the vaccine was the reason for the injury. See Capizzano, 440 F.3d at 1327. The government has not argued in Ms. Rotoli's case that a particular factor other than the vaccine was more likely than not the actual cause of Ms. Rotoli's AIH. Thus, because Ms. Rotoli has satisfied the Althen factors and met her burden as to causation-in-fact, and the government has failed to meet its burden as to alternative causation, Ms. Rotoli is entitled to recover for her injuries under the Vaccine Act. Walther, 485 F.3d at 1151 ("Once petitioners satisfy their burden of proving presumptive or actual causation by a preponderance of evidence, they are entitled to recover unless the Secretary shows, also

by a preponderance of evidence, that the injury was in fact caused by factors unrelated to the vaccine." (quotation omitted)); see also 42 U.S.C. § 300aa-13(a)(1).

2. David Myers (No. 99-631V)

a) Facts and Expert Testimony

The undisputed facts relevant to David Myers' case are briefly summarized below. Mr. Myers was born in 1961. In June 1992, tests of Mr. Myers' blood indicated two abnormal results: his ALT level was elevated, and his albumin was slightly above the normal range. On February 3, 1994, he received his first dose of the hepatitis B vaccination, after which he noticed some arm swelling and local pain. On February 17, 1994, Mr. Myers was treated for pruritis over his arms and legs; prednisone was ordered. By the following week, his pruritis had cleared, but he was prescribed dyazide for hypertension. On March 7, 1994, Mr. Myers received his second dose of the hepatitis B vaccination. On March 18, 1994, Mr. Myers went to an Immediate Care Center complaining of having had right upper quadrant pain for about three weeks, beginning after the first hepatitis B vaccination, but before the second. Blood tests at that time again showed elevated ALT and elevated albumin, as well as elevated alkaline phosphatase ("ALP").[20]

On March 28, 1994, Mr. Myers saw Dr. Daniel Maico for his right upper quadrant pain. Dr. Maico later stated that Mr. Myers' problems were not related to the hepatitis B

[20]Elevated ALT, albumin, and ALP are all consistent with liver problems.

vaccination. Blood drawn on March 31, 1994 indicated elevated asparatate aminotransferase ("AST") and ALT, but normal levels of albumin. On April 4, 1994, Mr. Myers' hypertension medication was changed from dyazide to lotensin because dyazide can impair liver function.

Blood work from April 26, 1994 indicated that the ALP was normal, and the AST and albumin were barely outside the normal ranges. Testing for hepatitis A, B, and C were negative. On May 25, 1994, Mr. Myers was diagnosed with mild hepatitis. Dr. Steven Jones attributed the mild hepatitis to the dyazide. Dr. Jones also discontinued the lotensin and started cardura. Blood work from May 1994 indicated that Mr. Myers' AST and ALP were within the normal range, while the ALT was elevated and the albumin remained slightly elevated. On June 15, 1994, the AST and ALP were again normal, while the ALT and albumin were slightly elevated.

On August 15, 1994, Mr. Myers received his third dose of the hepatitis B vaccination. On August 27, 1994, Mr. Myers went to the emergency room with fever, headache, and chills, and the doctor diagnosed acute viremia. On August 31, 1994, Dr. Jones diagnosed probable diverticulitis, prescribing cipro and flagyl. Blood work drawn at that time indicated much higher levels of AST, ALT and ALP than reported previously; the results of each were considerably outside normal range. Albumin, however, was at the low end of normal.

On September 23, 1994, a CT scan of Mr. Myers' abdomen was ordered, which showed no problems with his liver, spleen, pancreas, or kidneys. On October 10, 1994,

Mr. Myers asked Dr. Jared Kniffen, a gastroenterologist, whether the hepatitis B vaccinations could have caused the elevation in his liver function tests ("LFTs"). Dr. Kniffen had apparently acquired some literature – possibly from either Mr. Myers or from the manufacturer of the vaccine – that indicated elevated ALT levels have followed hepatitis B vaccination. Dr. Kniffen indicated that Mr. Myers' ALT level was over twice the maximum elevation described in the literature.

On November 8, 1994, Dr. Kniffen reported that Mr. Myers' LFTs were normal. Also on November 8, 1994, Dr. Jones indicated, "We are now reasonably certain that patient's elevated ALTs were due to his Engerix-B immunization." Myers Ex. 1 at 93. Approximately one year later, a November 3, 1995 liver biopsy revealed "scattered macrovesicular steatosis and minimal lobular hepatitis suggestive but not diagnostic of Hepatitis C." Myers Ex. 3 at 48. Dr. Rolland Dickson reviewed the biopsy results, ruling out hepatitis C because Mr. Myers had been tested for that disease. Dr. Dickson opined that "this is most likely steatohepatitis[.] I will check autoimmune markers to make sure he has not developed a precipitated [AIH], although this would be less likely." Myers Ex. 3 at 20. On January 5, 1996, Dr. Dickson also indicated that Mr. Myers' "right upper quadrant pain is without a good explanation" and that while "[i]t is possible that his liver biopsy findings could be explained by the vaccine, however, it would be very surprising to see this persist to this l[o]ng." Myers Ex. 3 at 5. On January 25, 1996, a Dr. Setzer stated,

I have participated in Mr. Myers' care for the last nine months. It seems he has

> suffered from a nonspecific hepatitis of uncertain etiology over the last two years. Specialists seem to concur at this time in their opinion hepatitis is related to a series of hepatitis B vaccinations that the patient received.

Myers Ex. 1 at 37.

Over the next few years, Mr. Myers continued to complain of right upper quadrant pain. The results of his LFTs varied from inside to outside the normal range. The pathologist reviewing a May 2000 liver biopsy stated that the tissue "represents mild chronic steatohepatitis which may have been caused by alcohol drinking, obesity or certain medications." Myers Ex. 20 at 12. However, at no time did any of Mr. Myers' treating physicians diagnose him with AIH.

Based on these undisputed facts, Dr. Bellanti testified that it was his opinion "to a reasonable degree of certainty" that the hepatitis B vaccine "caused or significantly contributed to the development of [Mr. Myers'] condition," which Dr. Bellanti called AIH, though "not a classic finding" thereof. Tr. 490. He indicated that, in his opinion, Mr. Myers suffered from "steatosis, with features suggestive of an immunologic component." Tr. 490. He concluded that "it is more likely than not that the hepatitis B vaccine could have contributed to [Mr. Myers' condition], based upon the temporal relationship to the onset of symptoms and no other likely cause identifiable." Tr. 490.

Based on the same undisputed facts, the respondent's expert, Dr. Koff, testified that, in his opinion, Mr. Myers suffered from non-alcoholic steatohepatitis ("NASH") instead of AIH and that there is no evidence to show that the hepatitis B vaccine causes NASH. As Dr. Koff testified, NASH is a metabolic liver disorder which falls under the

group of disorders known as nonalcoholic fatty liver disease. Tr. 532-33. According to Dr. Koff, NASH cannot be considered an autoimmune disease. Tr. 535. Moreover, Dr. Koff testified that, given that Mr. Myers had elevated liver enzymes prior to the receipt of the hepatitis B vaccine, it was reasonable to assume that his NASH predated the vaccine. Tr. 544-45. As a result, Dr. Koff concluded, the hepatitis B vaccine could not have caused Mr. Myers' condition.

b) Mr. Myers had NASH Instead of AIH, and the Petitioners Did Not Present Evidence of a Medical Theory Causally Connecting the Hepatitis B Vaccine with NASH.

The court finds that Mr. Myers suffered from NASH instead of AIH. Moreover, because Mr. Myers did not present any evidence of a medical theory by which the hepatitis B vaccine can cause NASH (a metabolic disease, as opposed to an autoimmune condition such as AIH), the court finds that Mr. Myers did not meet his burden under Althen's first prong.

The respondent's expert, Dr. Koff, testified that Mr. Myers had NASH, not AIH. None of Mr. Myers' treating physicians ever diagnosed him with AIH. Even the petitioners' expert, Dr. Bellanti, could not say that Mr. Myers presented a "classic finding" of AIH, testifying instead that Mr. Myers suffered from "steatosis, with features suggestive of an immunologic component." Tr. 490. The petitioners argue that, while they do not dispute Dr. Koff's diagnosis that Mr. Myers suffers from NASH, nor do they dispute that NASH is a different condition than AIH, Mr. Myers is nonetheless entitled to recover on the basis of the evidence that the hepatitis B vaccine caused him to suffer liver

damage "of some nature," regardless of the ultimate diagnosis. Mot. for Review 11, 9 & n. 13 (citing Kelley v. Sec'y of HHS, 68 Fed. Cl. 84, 100 (2005) ("The Vaccine Act does not require petitioners coming under the non-Table injury provision to categorize their injury; they are merely required to show that the vaccine in question caused them injury – regardless of the ultimate diagnosis.")).

However, the medical theory presented by the petitioners, as discussed at length above, was entirely concerned with linking an autoimmune disease, AIH – not a metabolic disease such as NASH, nor even "steatosis, with features suggestive of an immunologic component," see Tr. 490 – with the hepatitis B vaccine. While the court accepts the petitioners' medical theory as regards the autoimmune disease AIH, as discussed above, the court cannot extend its acceptance of the petitioners' medical theory to an entirely different, metabolic disease such as Mr. Myers' NASH. The record simply does not contain any evidence setting forth or supporting a theory by which the latter condition could be causally connected with the hepatitis B vaccine.

As a result, the court finds that Mr. Myers' failure to meet his burden with regard to the first Althen prong – a medical theory causally connecting his injury, NASH, with the hepatitis B vaccine – precludes his recovery for his injuries under the Vaccine Act.[21]

[21]The court notes that the evidence in Mr. Myers' case also raised questions as to whether he had demonstrated an appropriate temporal relationship between the onset of his disease and the hepatitis B vaccine. However, because the court finds, as discussed supra, that Mr. Myers has failed to satisfy the medical theory prong of Althen and therefore cannot recover for his injuries, the court does not have occasion to reach the remaining Althen factors in his case.

3. Colleen Torbett (No. 99-660V)

a) Facts and Expert Testimony

The undisputed facts relevant to Colleen Torbett's case are briefly summarized below. Ms. Torbett was born on March 15, 1957. On January 29, 1996, on the recommendation of the school system in which she was a physical education teacher, Ms. Torbett received her first dose of the hepatitis B vaccine. On February 9, 1996, she visited her doctor, complaining of having felt dizzy for a day and a half; she had also been taking Sudafed for two weeks (predating the vaccination) due to some mild sinus congestion. In February 1996, Ms. Torbett began taking diclofenac for her acne. On February 29, 1996, Ms. Torbett received her second dose of the hepatitis B vaccine. In an affidavit in 2000, Ms. Torbett stated that in April 1996, she noticed stiffness in her joints.

In July 1996, Ms. Torbett began taking minocycline for her acne. On August 20, 1996, she received her third hepatitis B vaccination. In her affidavit, Ms. Torbett stated that she started having joint pain after this third dose. On December 2, 1996, Ms. Torbett visited her doctor, complaining of soreness in her right elbow for about three weeks. She stated that the soreness was worse with activity. She was diagnosed with lateral epicondylitis, which is also known as tennis elbow. She followed up for her elbow pain three times, the last being February 10, 1997.

On August 15, 25, and 30, 1997, Ms. Torbett visited her doctor's office complaining of soreness in her joints. Blood tests from August 30, 1997 revealed two LFTs with elevated results. At some point during the summer of 1998, Ms. Torbett again

started taking diclofenac. Between November 1997 and October 1998, Ms. Torbett visited various doctors numerous times, complaining variously of headaches, fatigue, myalgia, arthralgias, allergies, asthma, and stiffness and tenderness in her wrists, elbows, and knees. On October 9, 1998, blood work showed abnormally high results for the LFTs. However, her anti-nuclear antibodies were negative. As a result of the elevated LFTs, Dr. Joseph Temming, a rheumatologist, recommended that Ms. Torbett stop using diclofenac. Dr. Temming considered the possibility that Ms. Torbett had AIH, but thought this condition was unlikely. Follow-up blood work on October 29, 1998 indicated that her LFTs were still elevated.

A November 19, 1998 liver biopsy revealed results "consistent with an autoimmune form of chronic hepatitis." Torbett Ex. 3 at 10. Upon receipt of these results, hepatologist Dr. Philip Williams believed that AIH was the most likely diagnosis and started Ms. Torbett on prednisone.[22] After three weeks on prednisone, Ms. Torbett's blood tests revealed an improvement in the level of her LFTs; Dr. Williams stated that this change supported the AIH diagnosis. After Ms. Torbett stopped taking prednisone in late December 1998 as a result of dyspepsia, her joint pain returned. Dr. Williams started Ms. Torbett on prednisone again on January 4, 1999. Blood tests in February 1999 revealed normal LFTs. On February 22, 1999, Ms. Torbett told her dermatologist that she had been diagnosed with AIH; the dermatologist noted that "this could possibly be

[22]Ms. Torbett's use of minocycline and diclofenac is not specifically mentioned in Dr. Williams' reports. However, Dr. Williams had the records from Ms. Torbett's doctor, Dr. Grainger, and her rheumatologist, Dr. Temming. Dr. Temming's reports do note that Ms. Torbett was taking minocycline and diclofenac.

secondary to the minocycline" and had her stop taking the drug. Torbett Ex. 5 at 7. On March 26, 1999, Ms. Torbett's blood tests again revealed normal LFTs.

On April 1, 1999, Dr. Williams considered her AIH to be "well controlled biochemically." Torbett Ex. 3 at 7. However, she still had joint pain and fatigue, and Dr. Williams suspected that she may have "other auto immune problems." Id. By 2001, Ms. Torbett's hepatitis had stabilized with the help of several medications. However, she is easily fatigued and has pain throughout her body, and she does not work.

Based on these undisputed facts, Dr. Bellanti testified that it was his opinion "to a reasonable degree of probability" that Ms. Torbett's AIH "was likely . . . due to the hepatitis B immunization, and [he] base[d] that opinion on the temporal relationship between her immunization, the onset of symptoms, which were medically appropriate, and there was no other likely cause identifiable in the record." Tr. 1231.

Based on the same undisputed facts, the respondent's expert, Dr. Zweiman, testified that the timing of the events in Ms. Torbett's case was strong evidence against an association between the vaccine and her symptoms. In addition, the respondent's expert, Dr. Koff, testified that, in his opinion, Ms. Torbett's AIH was likely caused by her use of the drug minocycline, a known cause of AIH, and not by the hepatitis B vaccine.

b) Ms. Torbett Failed to Establish a Proximate Temporal Relationship Between the Vaccine and Her Injuries by a Preponderance of the Evidence.

As noted above, as part of the petitioner's prima facie case of causation-in-fact, Althen requires "a showing of a proximate temporal relationship between vaccination and

injury," 418 F.3d at 1278, defined as "preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." de Bazan, 539 F.3d at 1352.

The court finds that Ms. Torbett failed to establish an appropriate temporal relationship between the vaccine and her injuries, as required under Althen. The court is persuaded that the purported early signs of Ms. Torbett's AIH were not related to her AIH. Ms. Torbett did not see a doctor for her alleged joint stiffness in April 1996 nor for her alleged joint pain in August 1996. Dr. Koff testified that it would be very hard for him to attribute the joint manifestations of which Ms. Torbett complained. Tr. 1447. For example, Dr. Koff testified that the joint pain she complained of in December 1996 (the first symptom documented in her medical records) was more likely attributable to her work as a physical education teacher than to the vaccine; he noted that tennis elbow has "never been reported as an extrahepatic articular joint manifestation of [AIH]." Tr. 1445. Similarly, Dr. Zweiman indicated that AIH patients "almost always had multiple joint involvement as their extrahepatic manifestation of [AIH]," Tr. 1500, and that the pain must be pronounced and prolonged before it could be considered arthralgia. Tr. 1503 ("Most experienced clinicians, particularly rheumatologists, will not accept a twinge that you have in a joint . . . when you get up in the morning that lasts for a few minutes as arthralgias. They demand a more pronounced and generally more prolonged expression of pain before they will call it arthralgias."). Dr. Zweiman also indicated that he believed

Ms. Torbett's work as a physical education teacher was likely the cause of the joint pain for which she saw a doctor in December 1996. Tr. 1506.

In light of the above testimony by the respondent's experts, the court finds that the earliest reliable indication of Ms. Torbett's AIH was the abnormal results of her blood tests on August 30, 1997. Moreover, the court finds that the August 30, 1997 test results were too far removed from the last dose of the hepatitis B vaccine on August 20, 1996 to infer causation from the temporal relationship.[23] Because the petitioners bear the burden to demonstrate a temporal relationship by a preponderance of the evidence under Althen, Ms. Torbett's failure to provide sufficiently robust temporal evidence is fatal to her prima facie case of causation-in-fact.

c) Ms. Torbett's AIH Was More Likely than Not Caused by Her Use of Minocycline Instead of by the Hepatitis B Vaccine.

In Ms. Torbett's case, the court also finds that, even assuming, arguendo, that she had met her burden under Althen, a preponderance of the evidence nonetheless supports a finding that her injuries were actually caused by her use of minocycline instead of by the hepatitis B vaccine. See de Bazan, 539 F.3d at 1352 (If the court finds that a petitioner has met her burden with regard to the Althen factors, "the burden shifts to the government to prove by a preponderance of the evidence that the petitioner's injury is due to factors unrelated to the . . . vaccine." (internal quotation omitted)).

[23] As noted above, Dr. Bellanti testified that a reasonable time to expect an adverse reaction is roughly fourteen to forty days after receipt of a dose of a vaccination. Tr. 34.

Specifically, the court is persuaded by the testimony of the respondent's expert, Dr. Koff, to the effect that minocycline caused Ms. Torbett's AIH. Dr. Koff presented several articles linking minocycline use and AIH, including a 2000 article entitled "Minocycline as a cause of drug-induced autoimmune hepatitis," by Neal S. Goldstein et al., in the American Journal of Clinical Pathology, which indicated that the hepatitis caused by minocycline is not distinguishable from the hepatitis caused by an autoimmune reaction.[24] Torbett Ex. C Tab 6. In light of this evidence, the court finds that the causal connection between minocycline and hepatitis is well-established and reliable.

As to whether minocycline was an alternative cause in Ms. Torbett's case in particular, the court finds that there was an appropriate temporal relationship between the earliest reliable signs of Ms. Torbett's AIH in August 1997 and the start of her minocycline use thirteen months prior in July 1996.[25] According to the Goldstein article, minocycline-related autoimmune disorders have been found to develop an average of two years after the initiation of drug therapy, with a range of three days to six years. Torbett Ex. C Tab 6 at 596-97. Despite being questioned about Ms. Torbett's minocycline use during the hearing, Dr. Bellanti failed to present any evidence to overcome the

[24]Indeed, Dr. Krawitt also listed minocycline as a cause of "hepatocellular injury that mimics [AIH]." Torbett Ex. A Tab 1.

[25]Ms. Torbett continued to take minocycline until February 1999, with a two-week break in October 1998. She discontinued use upon the recommendation of a doctor who thought it might be causing her AIH.

government's evidence in Ms. Torbett's case.[26] Dr. Bellanti acknowledged that minocycline can cause an immune-mediated reaction but failed to offer any explanation for his apparent belief that minocycline did not cause the AIH in Ms. Torbett's case. Tr. 1552-57. Thus, in light of the evidence that Ms. Torbett had been taking minocycline, a known cause of AIH, for thirteen months at the time her LFTs were found to be elevated, the court finds that Ms. Torbett's AIH was more likely than not caused by her use of minocycline instead of the hepatitis B vaccine.

In conclusion, because the court finds that (1) Ms. Torbett failed to meet her burden under Althen to establish a medically acceptable temporal relationship between the hepatitis B vaccinations and the onset of her AIH, and (2) preponderant evidence established that Ms. Torbett's injuries were actually caused by a factor other than the vaccine, specifically her minocycline use, the court finds that Ms. Torbett is not entitled to recover for her AIH under the Vaccine Act. See 42 U.S.C. § 300aa-13(a)(1); Althen, 418 F.3d at 1278.

4. Mona Porter (No. 99-639V)

a) Facts and Expert Testimony

The undisputed facts relevant to Mona Porter's case are briefly summarized below. Ms. Porter was born on September 28, 1962. On May 15, 1991, a dermatologist prescribed minocycline for Ms. Porter's acne. She took minocycline daily from May 15

[26]Unlike in Ms. Porter's case, discussed infra, Ms. Torbett was taking minocycline at the time her illness developed.

through October 18, 1991, at which time she was switched to an every-other-day dosage. On December 26, 1991, her LFTs were normal. Porter Ex. I. On May 11, 1992, her dermatologist indicated that she should "finish off" at the every-other-day dosage and then "discontinue." Porter Ex. I; Porter Ex. 36 at 9.

On July 8, 1992, because of her work in a physician's office, where her duties included drawing and preparing blood, Ms. Porter received her first dose of the hepatitis B vaccine. Blood tests taken that day revealed normal LFTs. On August 7, 1992, Ms. Porter received her second hepatitis B vaccination; she received her third dose on February 5, 1993. On March 1, 1993, blood tests revealed that Ms. Porter's liver enzymes were elevated well beyond the normal range. On March 5, 1993, her liver enzymes were approximately the same as on March 1, 1993: well outside the normal range. The March 5, 1993 tests also indicated that Ms. Porter was immune to hepatitis B and was not infected with hepatitis A, B, or C.

Ms. Porter began feeling nauseated, itching, and turning yellow on March 11, 1993. Blood tests on March 15, 1993 were again highly abnormal. On March 18, 1993, Ms. Porter saw a gastroenterologist, Dr. Richard Gilmore, who noted that she suffered from "acute hepatitis of undetermined etiology. The possibility that this is related to her vaccine cannot be excluded." Porter Ex. 8 at 1.

Blood work taken on April 1, 1993 showed that Ms. Porter had a positive anti-nuclear antibody and a positive smooth muscle antibody, both of which are consistent with a diagnosis of AIH. Her liver enzymes had decreased but were still above normal.

Ms. Porter resumed taking minocycline on April 23, 1993. Porter Ex. I. A liver biopsy was conducted on May 14, 1993, and the pathologist and Dr. Gilmore interpreted the results of that biopsy as consistent with AIH.

On July 7, 1993, Dr. Gilmore stated that Ms. Porter had been "placed on high dose steroids and over the past several weeks, her enzyme levels have dropped in half, but approximately by 90% since the peak of over 1000 was noted." Porter Ex. 8 at 2. In January 1994, Ms. Porter complained of psychiatric symptoms, which were diagnosed by an endocrinologist as secondary to the high dose steroids. Ms. Porter filed a workers' compensation claim against the physician's office where she had worked. The AIH continued to affect Ms. Porter for several years, but by September 2004, Ms. Porter's treating doctor recorded that her AIH had been in remission "for a long time." Porter Ex. 39 at 1. A December 2005 liver biopsy showed findings consistent with inactive or minimally-active chronic AIH.

Based on these undisputed facts, Dr. Bellanti testified that it was his opinion "to a reasonable degree of medical and scientific probability" that Ms. Porter's AIH "was likely due to her hepatitis B immunizations." Tr. 937-38. Dr. Bellanti noted that "[t]he temporal relationships are right, and the onset of symptoms is medically appropriate[,] and there's no other likely cause identifiable in the record." Tr. 938. With regard to her minocycline use, Dr. Bellanti testified that most minocycline-induced cases of AIH improve following discontinuation of the drug, contrary to what happened in Ms. Porter's case. Tr. 938.

Based on the same undisputed facts, the respondent's expert, Dr. Koff, testified that, in his opinion, Ms. Porter's liver problems were more likely caused by her use of minocycline, a known cause of AIH, than by the hepatitis B vaccine. In response to the petitioners' discontinuation of use theory, Dr. Koff indicated that Ms. Porter may have continued to take the minocycline for some time after the notation in her medical records that she was told to discontinue. Tr. 1028.

b) Ms. Porter Established a Proximate Temporal Relationship Between the Vaccine and Her Injuries by a Preponderance of the Evidence.

As noted above, as part of the petitioner's prima facie case of causation-in-fact, Althen requires "a showing of a proximate temporal relationship between vaccination and injury," 418 F.3d at 1278, defined as "preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." de Bazan, 539 F.3d at 1352. The court finds that Ms. Porter met her burden to show a medically acceptable temporal relationship between the vaccine and the onset of her injuries, as required under Althen. The undisputed evidence showed that Ms. Porter had blood tests indicating normal liver enzymes on July 8, 1992, the same day as she received her first dose of the hepatitis B vaccine. On February 5, 1993, she received her third dose of the vaccine. On March 1, 1993, Ms. Porter's blood tests indicated dramatically elevated liver enzymes. Thus, the evidence established that Ms. Porter's AIH began during the period

between July 8, 1992 and March 1, 1993. During this same period, Ms. Porter also received three doses of hepatitis B vaccine. Dr. Bellanti testified that a reasonable time to expect an adverse reaction is roughly fourteen to forty days after receipt of a dose of a vaccination. Tr. 34. Dr. Bellanti further testified that, in his expert opinion, the temporal relationship between Ms. Porter's immunizations and the onset of her symptoms was medically appropriate to infer causation.

The Federal Circuit does not require the petitioner to identify a specific date of onset of her illness, but merely a "medically acceptable timeframe" for the onset of symptoms. See de Bazan, 539 F.3d at 1352. Accordingly, in light of the evidence that Ms. Porter's liver enzymes spiked sometime during the timeframe in which she received three doses of the hepatitis B vaccine, the court finds that Ms. Porter demonstrated an appropriate temporal relationship between the onset of her illness and her receipt of the vaccine, as part of her prima facie case of causation-in-fact under Althen.

c) The Government Failed to Establish by a Preponderance of the Evidence that Ms. Porter's Minocycline Use Was More Likely than Not the Cause of Her Injuries.

As the government acknowledged at oral argument, if the court finds that a petitioner has met her burden with regard to the Althen factors, "the burden shifts to the government to prove by a preponderance of the evidence that the petitioner's injury is due to factors unrelated to the . . . vaccine." de Bazan, 539 F.3d at 1352 (internal quotation omitted). In Ms. Porter's case, as discussed above, the court has found that she met her burden under Althen to demonstrate a medical theory supported by a logical sequence of

cause and effect showing that the vaccine was the reason for her injury, as well as an appropriate temporal relationship between the vaccine and the onset of her illness. As a result, the burden now shifts to the government to prove alternative causation. For the reasons discussed below, the court finds that the government has not met that burden.

In Ms. Porter's case, the respondent argued, based on Dr. Koff's testimony, that a preponderance of the evidence showed that her AIH was not caused by the vaccine but was instead caused by another factor, her use of minocycline for her acne. As in Ms. Torbett's case, discussed above, Dr. Koff presented several articles linking minocycline use and AIH, including a 2000 article entitled "Minocycline as a cause of drug-induced autoimmune hepatitis," by Neal S. Goldstein et al., in the American Journal of Clinical Pathology, which indicated that the hepatitis caused by minocycline is not distinguishable from the hepatitis caused by an autoimmune reaction.[27] Porter Ex. F Tab 5. As the court found in Ms. Torbett's case, the causal connection between minocycline and hepatitis is well-established.

However, as to whether minocycline was an alternative cause in Ms. Porter's case in particular, the court finds by a preponderance of the evidence that Ms. Porter's injuries were not caused by her use of minocycline, based on her medical records and the medical literature indicating that symptoms typically resolve upon discontinuation of use of the drug. Specifically, according to Ms. Porter's medical records, she began taking

[27]Indeed, Dr. Krawitt also listed minocycline as a cause of "hepatocellular injury that mimics [AIH]." Porter Ex. D Tab 1.

minocycline on May 15, 1991. A blood test on December 26, 1991 indicated normal LFTs. Then, on May 11, 1992, Ms. Porter's dermatologist indicated that she should "finish off" at her every-other-day dosage of minocycline and then "discontinue." Porter Ex. I; Porter Ex. 36 at 9. Two months after being told to discontinue her minocycline, on July 8, 1992 (the day Ms. Porter received her first hepatitis B vaccine), Ms. Porter's LFTs were again found to be normal. It was not until March of 1993, after receiving the remaining two doses of hepatitis B vaccine, that Ms. Porter's LFTs were found to have spiked dramatically.[28,29]

Dr. Bellanti testified that, in his opinion, minocycline was not likely the cause of Ms. Porter's AIH, because a patient's symptoms can be expected to improve when minocycline use is stopped, which did not happen in Ms. Porter's case – her enzyme level spike happened during the period of time when she was not taking the drug. As Dr. Bellanti explained, "[t]he symptoms [of] the hepatitis [are] reversible upon cessation of the drug, which is the rule with most drug[-]induced pathologies." Tr. 939. In support of Dr. Bellanti's opinion, the petitioners submitted a chapter by James H. Lewis and Hyman J. Zimmerman entitled "Drug-induced autoimmune liver disease" from the textbook

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[28]To illustrate the spike in Ms. Porter's enzyme levels, on July 8, 1992, her AST and ALT were 21 and 22, respectively. On March 1, 1993, her AST and ALT spiked to 814 and 1221, respectively. Similarly, on March 15, 1993, her AST and ALT were 1012 and 1047, and on March 18, 1993, they were 968 and 1023, respectively. By April 2, 1993, her levels had dropped to 196 and 307. By October of 1993, her levels returned to the double digits, with her AST and ALT measuring 36 and 53, respectively. Porter Ex. I.

[29]On April 23, 1993, Ms. Porter resumed taking minocycline.

Autoimmune Liver Diseases, edited by Dr. Krawitt et al.[30] Porter Ex. 117. The chapter indicates that certain drugs, including minocycline, have been associated with a syndrome similar to autoimmune chronic hepatitis ("AICH"), but under "Clinical Features," the authors indicate that "until the effect of withdrawal of the respective drug is appreciated, drug-induced AICH is indistinguishable from cryptogenic AICH." Porter Ex. 117 at 627-28, 630 (emphasis added). Similarly, the chapter indicates that "Characteristics of Drug-Induced AICH" include "[r]esolution on withdrawal of the drug." Porter Ex. 117 at 630.

In Ms. Porter's case, the evidence in her medical records showed that Ms. Porter discontinued minocycline, but she nonetheless developed symptoms of hepatitis after that time. Because the burden to demonstrate that minocycline was the cause-in-fact of Ms. Porter's injuries falls on the government, the court finds that, to prevail on such a theory, the respondent must do more than suggest that it is possible that Ms. Porter was not taking the medication in compliance with her doctor's instructions, where, as here, there is no evidence in the record to support such an assertion. Nor may the government meet its burden merely by suggesting that Ms. Porter could have been one of the rare cases in which symptoms caused by minocycline use do not improve upon discontinuation. The government's burden is to demonstrate, not merely that an alternative cause could have been at play, but that it was more likely than not that her symptoms were caused in fact by an alternative cause. de Bazan, 539 F.3d at 1354 ("[S]uccessfully proving the elements of

[30]Though the Lewis and Zimmerman chapter was late-submitted in Ms. Porter's case, it had been previously filed in Ms. Torbett's case – by the respondent – as Torbett Ex. C Tab 1.

the Althen test establishes that the medical evidence indicating that the vaccine may have caused the petitioner's injury is strong enough to infer causation-in-fact absent proof that some other factor was the actual cause. The government then must provide that proof by identifying a particular such factor (or factors) and presenting sufficient evidence to establish that it was the sole substantial factor in bringing about the injury." (first emphasis in original; second emphasis added; citation omitted)). The court finds that the government has failed to meet that evidentiary burden in Ms. Porter's case.

Thus, because Ms. Porter has met her burden under the Althen factors, and the government has failed to present preponderant evidence showing that minocycline was the sole substantial factor in bringing about Ms. Porter's injury, the court finds that Ms. Porter is entitled to recover for her AIH under the Vaccine Act. See 42 U.S.C. § 300aa-13(a)(1); de Bazan, 539 F.3d at 1354.

5. Allison Hager (No. 01-307V)

a) Facts and Expert Testimony

The undisputed facts relevant to Allison Hager's case are briefly summarized below. Ms. Hager was born on October 10, 1986. At age eleven, Ms. Hager received her first dose of the hepatitis B vaccine on November 17, 1997, and her second dose on December 17, 1997. Ms. Hager's mother indicated in an affidavit that Ms. Hager was healthy until March or April of 1998, at which time Allison began to have stomach pain and nausea. Ms. Hager's own affidavit indicated that she was feeling fine in May 1998. On September 28, 1998, Ms. Hager was examined for upper abdominal pain since late

July or early August, as well as a decrease in appetite. Her doctor, Dr. Hope Tinker, diagnosed gastritis and prescribed Zantac. The next day, September 29, 1998, Ms. Hager received the third dose of hepatitis B vaccine.

On October 19, 1998, Ms. Hager returned to Dr. Tinker's office complaining of abdominal pain, nausea, and anorexia. Her Zantac was increased. Blood tests taken that same day revealed that her liver enzymes were elevated. On October 28, 1998, Dr. Tinker indicated, "Certainly Sept. HEP B shot could have been contributory to [elevated LFTs;] though rarely reported, have seen before. Doesn't explain initial illness," which the doctor indicated had begun in late July or August, prior to the third dose of hepatitis B vaccine. Hager Ex. 1 at 16.

On November 5, 1998, Ms. Hager saw Dr. Jose Barrios, an assistant professor of pediatrics at the University of Missouri Hospital and clinics. Ms. Hager's mother told him that her daughter was in good health until July or August 1998. He diagnosed gastritis and noted her elevated LFTs. Though Dr. Barrios recommended repeating the LFTs in a few months, Ms. Hager did not do so. Her mother indicated that Ms. Hager was feeling much better and not taking Zantac; she felt well until late July 1999. Around August 1, 1999, Ms. Hager began experiencing a rash; she received various treatments, and by September 14, 1999, her rash had cleared.

In a September 14, 1999 appointment, an associate of Dr. Tinker noted that Ms. Hager was jaundiced in her eyes and referred her to a specialist. That same day, Ms. Hager saw Dr. Michael Cooperstock. He stated that she had jaundice and a multiform

rash and that he believed that "[i]t is very likely that she has hepatitis, perhaps hepatitis A or C. Far less likely, might be drug induced hepatitis, lupus hepatitis, or other causes of liver disease." Hager Ex. 2 at 6. Bloodwork ordered by Dr. Cooperstock revealed that most liver enzymes were elevated, including very high levels for ALP, and that she did not have hepatitis A or C. On September 16, 1999, Dr. Barrios reported that Ms. Hager had a rash and that she was jaundiced and fatigued. An ultrasound the next day revealed a persistently contracted gallbladder and dilation of the common hepatic bile duct.

On September 23, 1999, Ms. Hager was admitted to the hospital with a macropapular rash over her lower extremities and an enlarged liver. A liver ultrasound that day revealed an enlarged echogenic liver, a normal gallbladder, and debris in the common bile duct. A liver biopsy the next day was consistent with biliary obstruction, and some fibrosis was noted. An endoscopic retrograde cholangiopancreatography ("ERCP") on September 29, 1999 indicated dilation in the common bile duct. Ms. Hager remained at the hospital until October 1, 1999. When she was discharged, Dr. Thomas Foy indicated that any problem was primarily obstructive.

On October 27, 1999, Ms. Hager was readmitted to the hospital with nausea and an itchy rash over most of her body; she was also jaundiced. Her LFTs were elevated. On October 29, 1999, Ms. Hager was discharged; the discharge notes indicated "Jaundice and elevated LFT's most likely [secondary] to [AIH]." Hager Ex. 7 at 22. Dr. Foy believed Ms. Hager had AIH; blood tests during her previous admission showed positive results for anti-nuclear antibodies and smooth muscle antibody. Dr. Foy prescribed prednisone

and Imuran.

On November 1, 1999, Dr. Barrios reported that Ms. Hager's LFTs, jaundice, activity level, and appetite were all improved. Dr. Foy indicated that her improvement is "good evidence that at least a component of her liver disease is probably from [AIH]." Hager Ex. 7 at 259. Dr. Foy also noted that the doctor who performed Ms. Hager's ERCP stated that Ms. Hager "did not have [a] biliary tree at this time consistent with sclerosing cholangitis." Id. On January 7, 2000, her gastroenterologist wrote that Ms. Hager "has had good response of what appears to be smooth muscle antibody positive [AIH] and we can begin weaning her steroids." Hager Ex. 7 at 272.

In November 2000, Ms. Hager told Dr. Barrios she was having loose stools. On approximately December 9, 2000, Ms. Hager began having blood in her stools and more diarrhea, as well as abdominal pain. At that time, her ALP was very high, and her AST was high. Following a December 19, 2000 colonoscopy, Ms. Hager was diagnosed with ulcerative colitis. On January 3, 2001, Dr. Barrios stated that Ms. Hager had "ulcerative colitis and probably sclerosing cholangitis." Hager Ex. 6 at 194. A liver biopsy and transhepatic cholangiogram under ultrasound on March 29, 2001 revealed "a pattern more suggestive of distortion due to cirrhosis than to sclerosing cholangitis." Hager Ex. 9 at 475-76. Reports from the hospital's hepatology clinic on September 27, 2001 and January 9, 2002 indicated a diagnosis of "end stage liver disease and ulcerative colitis," Hager Ex. 9 at 27, and "inflammatory bowel disease and chronic liver disease, felt to be a combination of both sclerosing cholangitis and an autoimmune parenchymal process,"

Hager Ex. 9 at 14, respectively. In 2004, a doctor stated that, although Ms. Hager was originally diagnosed with AIH, the course of her disease was "felt to be more consistent with sclerosing cholangitis." Hager Ex. 11 at 618. Ms. Hager is on a list to receive a liver transplant.

Based on these undisputed facts, Dr. Bellanti testified that it was his opinion that the hepatitis B vaccine "can cause or significantly have contributed to the development of an [AIH] or cholangitis or both. Tr. 220. Dr. Bellanti testified that, in his opinion, Ms. Hager's AIH "and associated sequela were most likely due to her hepatitis B immunization, and this is based upon the temporal relationships between her immunizations, the onset of symptoms is medically appropriate, and there is no other likely cause that could be identified in the record." Tr. 220. In Ms. Hager's case, Dr. Bellanti emphasized that his opinion was "based upon . . . new clinical studies related to the interaction of environmental, genetic and immunologic factors which play a role in the pathogenesis of autoimmune liver disease." Tr. 220.

Based on the same undisputed facts, the respondent's expert, Dr. Koff, testified that, in his opinion, Ms. Hager never had AIH, but that she has either primary sclerosing cholangitis ("PSC") or autoimmune sclerosing cholangitis, instead.[31] Dr. Koff further

[31]Specifically, Dr. Koff stated that Ms. Hager

> has either [PSC], a chronic cholestatic liver disease . . . of unknown etiology characterized by inflammation and fibrosis of the biliary tree, or a disorder called autoimmune sclerosing cholangitis, which shares many features with [PSC]. Both are thought to be immunologically mediated. In both, large or small bile ducts are affected, antinuclear antibodies may be present and inflammatory bowel disease . .

opined that, like AIH, neither form of cholangitis has been shown to be caused by the hepatitis B vaccine. Dr. Koff also stated that Ms. Hager's medical records suggest a "predisposition to autoimmune diseases" dating back to her early childhood. Hager Ex. C at 2, 1. By contrast, Dr. Berger, also an expert for the respondent, indicated that, in his opinion, Ms. Hager has "an 'overlap' syndrome of [AIH] . . . with autoimmune sclerosing cholangitis." Hager Ex. A at 4. However, Dr. Berger, like Dr. Koff, indicated that, in his opinion, the evidence does not show that the hepatitis B vaccine can cause AIH or autoimmune sclerosing cholangitis.

b) Ms. Hager Suffered from AIH that Evolved into PSC or Autoimmune Sclerosing Cholangitis, So the Petitioners' Medical Theory Connecting the Vaccine with AIH Applies to Ms. Hager's Injuries.

The court finds that Ms. Hager suffered from AIH which evolved into PSC or autoimmune sclerosing cholangitis. Moreover, by contrast to Mr. Myers' case, in which the diagnosis of NASH differed in kind from the illness (AIH) identified in the petitioners' medical theory, in Ms. Hager's case, because her illness evolved from and is on a spectrum of diseases with AIH, the court finds that the medical theory accepted by the court with regard to AIH is sufficient to meet Ms. Hager's burden as to the first prong of Althen.

. is common. Whether these are truly different disorders or whether one can evolve into the other remains uncertain.

Hager Ex. A at 2 (emphasis added).

Specifically, the court is persuaded by the substantial body of peer-reviewed medical literature indicating that AIH has been known to evolve into or overlap with PSC.[32] See Hager Ex. 18 (Evolution of Autoimmune Hepatitis to Primary Sclerosing Cholangitis: A Sequential Syndrome, by Ayman A. Abdo et al., 36 No. 6 Hepatology 1393 (2002)); see also Hager Exs. 17, 19, 25, H. In addition, the court is persuaded by the testimony of one of the respondent's experts, Dr. Berger, who stated that Ms. Hager has "an 'overlap' syndrome of [AIH] . . . with autoimmune sclerosing cholangitis."[33] Hager Ex. A at 4. The court also notes that several of Ms. Hager's treating physicians, including Dr. Foy, Dr. Tinker, and a gastroenterologist, stated that Ms. Hager had AIH at

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[32]In addition, the court is persuaded by Dr. Koff's testimony to the effect that autoimmune sclerosing cholangitis

> shares many features with [PSC]. Both are thought to be immunologically mediated. In both, large or small bile ducts are affected, antinuclear antibodies may be present and inflammatory bowel disease . . . is common. Whether these are truly different disorders or whether one can evolve into the other remains uncertain.

Hager Ex. A at 2. Thus, the court need not decide which of the two conditions – PSC or autoimmune sclerosing cholangitis – Ms. Hager's AIH evolved into or overlapped with.

[33]Specifically, Dr. Berger stated:

> She initially responded well to treatment with prednisone and imuran, which are usually used for [AIH]. . . . [I]n retrospect, it seems quite clear that this child has an "overlap" syndrome of [AIH] with autoimmune sclerosing cholangitis (ASC). This is a well-reported association . . . . Allison's case, with hyperglobulinemia and positive anti-smooth muscle antibodies[,] seems most similar to those described by McNair et al. ["Autoimmune hepatitis overlapping with primary sclerosing cholangitis in five cases," 93 Am. J. Gastroenterol. 5:777-84 (May 1998)].

Hager Ex. A at 4.

some point in the course of her illness. See Andreu, 569 F.3d at 1375 (Testimony of treating physicians is "quite probative.").

Thus, because the evidence in Ms. Hager's case showed that her condition evolved along an established spectrum from AIH to the more severe condition of PSC or autoimmune sclerosing cholangitis, the court finds that the petitioners' medical theory causally connecting AIH and the hepatitis B vaccine, accepted by the court as set forth above, applies to Ms. Hager's injuries as well. Accordingly, the court finds that Ms. Hager has satisfied her burden as to the medical theory prong of Althen.

c) Ms. Hager Established a Proximate Temporal Relationship Between the Vaccine and Her Injuries by a Preponderance of the Evidence.

The court next turns to the evidence of a temporal relationship between the onset of Ms. Hager's illness and her receipt of the hepatitis B vaccine. As noted above, as part of the petitioner's prima facie case of causation-in-fact, Althen requires "a showing of a proximate temporal relationship between vaccination and injury," 418 F.3d at 1278, defined as "preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." de Bazan, 539 F.3d at 1352. The court finds that Ms. Hager has met her burden to show such a relationship by a preponderance of the evidence.

Ms. Hager received her three doses of the vaccine on November 17, 1997,

December 17, 1997, and September 29, 1998. Three weeks after her third dose of the vaccine, on October 19, 1998, Ms. Hager visited Dr. Tinker's office complaining of abdominal pain, nausea, and anorexia. Blood tests taken that same day revealed that her liver enzymes were elevated. On October 28, 1998, Dr. Tinker indicated, "Certainly Sept. HEP B shot could have been contributory to [elevated LFTs;] though rarely reported, have seen before." Hager Ex. 1 at 16. Indeed, Dr. Bellanti testified that Ms. Hager's medical records indicated that

> there seems to be a definite progression of events that occurred following the second immunization of hepatitis B vaccine. Whether or not something was going on before the third immunization where she was experiencing abdominal pain, fullness, nausea, since July of 1998, I honestly don't know. But certainly something happened after the third vaccine. Three weeks after [the third vaccine] she had an exacerbation of abdominal pain, nausea, and the blood tests at that time revealed the increased liver function studies[,] and the whole cascading set of events that transpired after it spoke to a progression of an inflammatory autoimmune disease that progressed on to cirrhoses, dilated esophageal varices, portal hypertension, and then to top it off another autoimmune disease, ulcer colitis.

Tr. 219 (emphasis added); see also Tr. 238 ("It was an exacerbation three weeks after number three vaccine, sever[e] enough to give her severe abdominal pain to be seen by a physician and to have blood drawn to do a metabolic panel, to do liver function studies.").[34,35]

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[34]As noted above, Dr. Bellanti testified that a reasonable time to expect an adverse reaction is roughly fourteen to forty days after receipt of a dose of a vaccination. Tr. 34.

[35]A liver biopsy performed on September 24, 1999 showed fibrosis, indicating a disease that had been present for at least a year, according to Dr. Koff. However, in that same biopsy, no cirrhosis was noted. Dr. Koff testified that a showing of cirrhosis would indicate a disease that

Based on the evidence that Ms. Hager's symptoms flared three weeks after her third dose of the vaccine, combined with the statement by Ms. Hager's treating physician, Dr. Tinker, that the vaccine "certainly" could have contributed to her symptoms, Hager Ex. 1 at 16, and the expert testimony of Dr. Bellanti that "certainly something happened after the third vaccine," Tr. 219, the court finds that Ms. Hager has met her burden to show a temporal relationship between her illness and the vaccine.[36]

In conclusion, in addition to finding that Ms. Hager met her burden of showing a medical theory causally connecting the vaccine and her AIH progressing to PSC or autoimmune sclerosing cholangitis, the court finds that Ms. Hager met her burden under Althen to establish a medically acceptable temporal relationship between the hepatitis B vaccinations and the onset of her illness. In addition, in setting forth the medical theory and temporal relationship, Ms. Hager established by a preponderance of the evidence a logical sequence of cause and effect showing that the vaccine was the reason for the injury. See Capizzano, 440 F.3d at 1327. The government has not argued in Ms. Hager's case that a particular factor other than the vaccine was more likely than not the actual cause of her illness. Thus, because Ms. Hager has satisfied the Althen factors and met her

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had been present "for years." Tr. 435. By contrast, eighteen months later, on March 29, 2001, a biopsy and transhepatic cholangiogram under ultrasound did show "a pattern more suggestive of distortion due to cirrhosis than to sclerosing cholangitis." Hager Ex. 9 at 475-76.

[36]Having found that Ms. Hager has met her burden to show actual causation under Althen, the court does not have occasion to reach the question of whether Ms. Hager might prevail under a significant aggravation theory.

prima facie burden as to causation-in-fact, and the government has failed to meet its burden as to alternative causation, Ms. Hager is entitled to recover for her injuries under the Vaccine Act. Walther, 485 F.3d at 1151 ("Once petitioners satisfy their burden of proving presumptive or actual causation by a preponderance of evidence, they are entitled to recover unless the Secretary shows, also by a preponderance of evidence, that the injury was in fact caused by factors unrelated to the vaccine." (quotation omitted)); see also 42 U.S.C. § 300aa-13(a)(1).

CONCLUSION

In these five cases, the court hereby **ORDERS** as follows:

1) **Ms. Rotoli (No. 99-644V):** Based on the court's findings pursuant to 42 U.S.C. § 300aa-12(e)(2)(B), as set forth above, Ms. Rotoli's case is remanded to the special master for a determination of damages consistent with this Opinion and Order. The special master shall issue his decision on remand within 90 days of the original date of filing of this Opinion and Order, in accordance with RCFC, App. B Rule 28(b).

2) **Mr. Myers (No. 99-631V):** Based on the court's findings pursuant to 42 U.S.C. § 300aa-12(e)(2)(B), as set forth above, the clerk of the court is instructed to enter judgment for the government in Mr. Myers' case.

3) **Ms. Torbett (No. 99-660V):** Based on the court's findings pursuant to 42 U.S.C. § 300aa-12(e)(2)(B), as set forth above, the clerk of the court is instructed to enter judgment for the government in Ms. Torbett's case.

4) **Ms. Porter (No. 99-639V):** Based on the court's findings pursuant to 42 U.S.C. § 300aa-12(e)(2)(B), as set forth above, Ms. Porter's case is remanded to the special master for a determination of damages consistent with this Opinion and Order. The special master shall issue his decision on remand within 90 days of the original date of filing of this Opinion and Order, in accordance with RCFC, App. B Rule 28(b).

5) **Ms. Hager (No. 01-307V):** Based on the court's findings pursuant to 42 U.S.C. § 300aa-12(e)(2)(B), as set forth above, Ms. Hager's case is remanded to the special master for a determination of damages consistent with this Opinion and Order. The special master shall issue his decision on remand within 90 days of the original date of filing of this Opinion and Order, in accordance with RCFC, App. B Rule 28(b).

IT IS SO ORDERED.

s/Nancy B. Firestone
NANCY B. FIRESTONE
Judge